Steven Posnack, MS, MHS
Acting Assistant Secretary for Technology Policy
Office of the Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Washington, DC 20416

RE: United States Core Data for Interoperability (USCDI) Version 6 Draft

Dear Acting Assistant Secretary Posnack,

On behalf of the American Medical Informatics Association (AMIA), we are pleased to provide feedback to the Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) on its Draft USCDI v6.

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

Submitted recommendations for each data class and element as summarized below. Under data elements, the data class it is associated with is in parentheses.

General Comments:

- We suggest beginning work on the inclusion of Environmental Determinants of Health (EDOH) in USCDI. EDOH would parallel Social Determinants of Health (SDOH), which are beginning to be included in EHRs. Collectively, these factors could be labeled "Determinants of Health."
- There is limited content for EDOH in existing standards[1]. We recommend considering existing frameworks, such as the United Nations Office for Disaster Risk Reduction (UNDRR) Hazard Information Profiles, to begin sourcing EDOH content for EHRs.

- To support nationwide interoperability and data consistency, we suggest developing standardized implementation frameworks should be considered, including formal FHIR profiles, authoritative implementation guides, and validated mapping tools for newly introduced data elements, such as the Unique Device Identifier and Portable Medical Order. These resources could serve to minimize technical variability, reduce implementation burden, and ensure uniform adoption across health information systems.

[1]Lokmic-Tomkins Z, Block LJ, Davies S, et al. Evaluating the representation of disaster hazards in SNOMED CT: Gaps and opportunities. J Am Med Inform Assoc. 2023;30(11):1762-1772. doi:10.1093/jamia/ocad153

- AMIA recommends that ASTP/ONC adopt a structured and collaborative roadmap for the integration of USCDI+ into future versions of USCDI. This approach should prioritize enhancing interoperability and improving the quality and utility of healthcare data exchange. A well-defined integration pathway will help ensure all the domains of USCDI+ are considered and matches ASTP/ONC's goal for USCDI+, which "aims to increase the use of standardized and harmonized data to enable agencies and the health care system to exchange critical information more easily and make better informed decisions."

Data Class

Clinical Notes:

- Data quality is fundamental to meaningful interpretation of care notes. AMIA recommends the addition of Admission Note and Anesthesia Note as Data Elements to Clinical Notes.
- Included provenance should disclose when "notes" are generated from pick lists, AI generated, or have been cut and pasted from elsewhere through a stamp generated by the EHR tool. Consideration of computer assisted (e.g. voice recognition) and emerging (e.g. generative AI) machine-assisted note composition and the associated provenance needs. Is also recommended. This standard assists tracking the clinical notes journey and how they are completed by the care team. Certain electronic health records management systems track the percentage of clinical notes that are copied/pasted.
- Since there are few standards for structured data elements that describe environmental and occupational exposures (e.g., air quality, air pollution, heat exposure, maximum temperature days, heat-related illness, per- and polyfluoroalkyl substances and other chemicals, lead and other heavy metal exposures, water quality, flooding, extreme weather events, etc.), we suggest consideration of mentioning these data in clinical notes.

Diagnostic Imaging:

- AMIA suggests that ASTP/ONC specify which provider types are referred to as "credentialed professional." Additionally, ASTP/ONC may wish to include an element to signify any artificial intelligence or algorithmic component of imaging reports, along with a requirement for generation of a report with prioritized results. For software that requires FDA approval, the Unique Device Identification number should be included.
- AMIA suggests modifying the title to "Imaging" to encompass all types of imaging in the healthcare setting (including for therapeutic interventions). Imaging can also extend to other types of data that inform health outcomes, such as environmental, occupational, or climate data to include satellite images or sensor imaging.

Goals and Preferences:

- This data class is defined as "desired state to be achieved by a patient." AMIA encourages ASTP/ONC to consider renaming this category to "Person Goals and Preferences." Person-centric goals reflect goals over time, not just when the person is a patient. AMIA continues to believe that "goals" should be defined and differentiated (i.e.: person-defined or generated, clinician-captured, obtained through interdisciplinary team members such as care coordinators or social workers, or goals from clinician orders or advanced care

planning documents). Identifying the source of the information in this data class is central to interpreting the outputs. For example, the desired goal or outcome stated by the person and captured directly from the person, may or may not have the same perceived value as goals captured from submitted advanced care planning documents or prior clinician orders. There are increasingly structured and validated ways to capture goal setting. The National Committee for Quality Assurance has developed outcome measurements with the patient central to the research.[2] AMIA suggests aligning with emerging standards in this area as we have seen organizations have success, for example, having advanced directives toward goal setting.

- Patient Goals need to align with Treatment Intervention Preference
- Clarify in each element when these are the person's ("patient's") goals & preferences
- Clarify the intent of the first element - Person's desired outcomes of their care - and the third element - wishes when unable to participate in medical decision making for whatever reason
- Separate and distinct from Care Team (including shared decision making) goals, which is captured under the Patient Summary and Plan Data Class.
- Patient Goals should also include Patient Authorized Representative if the patient is unable to communicate their desired outcomes.

Provenance:

- The information contained in this data class is a critical underpinning for all other data classes and elements. Beyond the elements of author time stamp and author organization, the role of the author should be identified. The author may or may not be an identified member of the care team, especially highlighting the possibility of patients and authorized family or caregivers as potential contributors of health data. The author may also be health devices, mobile health applications and remote patient monitoring devices or sensors (e.g., in home, body worn, air quality sensors) or satellite imaging. AMIA recommends creating role buckets, or groupings, such as "patient/caregiver, devices, sensors, satellite imaging, or health system employee/contractor/affiliate" understanding there are no current standards to define roles.
- Provenance needs more explanation . There is a care paradigm change and needs to better reflect what is happening in the real world with an emphasis on longitudinal course of care.
- AMIA also recommends Provenance needs identity and the role of the actor/author/entity generating the Element is implied but not explicit. Need to tease out other helpful metadata for each USCDI element.

Problems:

- There are limitations on the capture of diagnosis information. ASTP/ONC's inclusion of SNOMED International, Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, March 2022 Release and International Classification of Diseases ICD-10-CM 2022 as vocabulary standards represent an important step, but in reality, the problem or reason for seeking medical attention is often not documented in the health record. In reality, "Actual Date of Diagnosis" and "Date of Resolution" are typically not known or are

[2] https://www.ncqa.org/hedis/reports-and-research/pco-measures/

captured without adequate context to determine accuracy. These elements are included but may not yield any accurate information.

- The elements Date of Diagnosis and Date of Resolution are not useful as such. Consider when (days, weeks, months) first recognized or addressed (Provenance - by whom), and whether resolved or chronic, or the like. Recognize in the context of an interoperable document or data set these represent snapshots in time. Longitudinal observations and trajectories are not well represented in EHRs.

Participation in Clinical Trials:

- AMIA suggests that ASTP/ONC add "Participation in Clinical Trials" as a data class for inclusion in USCDI v6. It is necessary to capture the unique clinical scenarios of participants enrolled in clinical research studies.

Patient Demographics:

- ASTP/ONC references applicable vocabulary standards as the CDC Race and Ethnicity Code Set Version 1.2 (2021), and Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised October 30, 1997. The CDC document outlines self-identified race and ethnicity and observer-identified race and ethnicity. **ASTP/ONC might consider emphasis on self-identification or patient verified race and ethnicity data.** AMIA encourages ASTP/ONC to ensure that vocabulary standards are updated routinely as standards change and evolve, to avoid stigmatizing language and ensure health equity and respect for all people.

- AMIA suggests that ASTP/ONC add "Veteran Status" as a data element for inclusion under Patient Demographics.

Medical Devices:

- AMIA recommends a more thorough breakdown of the Medical Devices Data Class. For medical devices, there should be a distinction between permanent versus temporary data classes. Temporary devices for example PICC line, indwelling foley and suprapubic catheters, and wound vacs. Medical applications should also be included as they are considered medical digital devices, such as digital therapeutics, standard language models, payor exchanges, what is included and excluded in this category.

Data Elements

Care Plan (Under Patient Summary and Plan):

- AMIA supports the expansion of patient summary and plan data within USCDI v6, particularly as it relates to improving care coordination and continuity. However, we urge

careful consideration regarding the proposed addition of a "Care Plan" data element to ensure alignment with existing USCDI components:

- AMIA finds the terminology used in the proposal unclear. Specifically, the reference to “prioritized problems” lacks clarity. It is ambiguous whether this refers to entries on a problem list, broader health concerns, elements within the care plan itself, or another construct. We recommend removing the word “prioritized” to avoid confusion. While a care plan should acknowledge relevant clinical issues, it may not always do so through an explicitly prioritized list of problems.
- We note the potential overlap between the proposed Care Plan data element and several existing data classes in USCDI, such as Assessment and Plan of Treatment, Patient Goals, Health Concerns, and Care Experience Preferences. We recommend that ASTP/ONC provide clear definitions and scope for the Care Plan element and clarify how it relates to or differs from these existing elements.
- We also encourage ASTP/ONC to explicitly include patient values, preferences, and goals in the structure of the care plan, and to clarify how this inclusion aligns with the existing “Patient Goals” data element. This would enhance the person-centeredness of the data while reducing ambiguity.
- We request that ASTP/ONC provide clarity on how care plans are to be represented and exchanged in implementation. Certified EHRs currently support care planning using a range of formats, including structured data, narrative text, or a combination of both. Any standard must consider this diversity and allow flexibility to ensure that care plans can be transmitted and aggregated meaningfully and efficiently. Imposing overly rigid data structuring requirements could create technical challenges that hinder, rather than support, interoperability.
- ASTP/ONC should also provide guidance on the appropriate use of structured fields versus narrative text, particularly for situations in which data must be aggregated across systems. Any standard should support scalability and adaptability across clinical settings and use cases.

Portable Medical Order (Under Orders):

- AMIA supports the inclusion of this element as currently defined, recognizing its value in conveying essential clinical information without imposing undue burden on physicians. However, we encourage ASTP/ONC to consider renaming the element to better reflect its relationship to life-sustaining care. A more intuitive label could enhance clarity and alignment with its intended purpose.

Unique Device Identifier (Under Medical Devices)

- We commend ASTP/ONC efforts for broadening the UDI requirement to cover all medical devices, not just implants. This important step improves traceability, enhances safety monitoring, and strengthens recall efforts.
- At the same time, we share some concerns about the lack of clarity regarding the full scope of this expansion. It is uncertain whether UDIs will be required for all diagnostic and therapeutic devices, including those integrated through laboratory information systems

(LIS) and point-of-care (PoC) systems, many of which do not currently support UDI functionality.

- We caution that expanding UDI requirements without clear guidance could create workflow challenges and increase reliance on manual data entry, reducing efficiency and data quality. We encourage ONC to work with stakeholders on a phased, use-case-driven implementation approach that reflects operational realities and minimizes undue burden.

Facility Address (Under Facility Information):

- As highlighted by the Alliance for Nursing Informatics (ANI), specific considerations are needed for mobile and emergency medical services (EMS), which often operate without a fixed physical address. Excluding EMS from facility-based exchange frameworks risks omitting critical data related to care provided at the initial point of patient contact. To ensure comprehensive and accurate data representation, the following recommendations are proposed:
    - Clarify address representation for non-traditional care settings: Provide guidance on how to accurately represent healthcare facilities that span multiple physical locations or operate without a fixed address, such as mobile units and EMS services.
    - Define address types required for USCDI exchange: Specify which address types are applicable and required in various use cases, including patient encounters, provider directories, and regulatory or public health reporting.
    - Introduce a standardized data element for address type: Consider establishing a structured data element to indicate the purpose of each address (e.g., "mailing," "service location," "billing") to enable systems to correctly interpret and utilize address data across exchange scenarios.

Assessment and Plan of Treatment (Under Patient Summary and Plan):

- There is a need to recognize that the burden of data collection falls on the end-user clinician. Data should be derivative of the clinical workflow. When conducting a **Social Determinants of Health (SDOH) screening or assessment**, AMIA encourages ASTP/ONC to ensure that vocabulary standards avoid stigmatizing language and ensure respect for all people. Further, as standards change and evolve, AMIA encourages routine updates and alignment with HL7 FHIR Accelerator, The Gravity Project.

"Environmental Risk Assessment" (Under Health Status Assessment):

- Consider adding "Environmental Risk Assessment" (Under Health Status Assessment). We use Heat Risk Assessment as one example[3]. The following clinical value sets allow for clinicians to proactively screen and flag high-risk patients during routine medical appointments or in preparation for forecasted extreme maximum temperature days or heat waves. Proactive screening allows clinicians to adjust medication regimens, especially for

[3] https://www.nachc.org/nachc-content/uploads/2024/09/NACHC_EHR-Heat-Messaging-Guide.pdf

medication with adverse effects to high temperatures, and implement targeted educational interventions to manage risk factors:

  - Heat Related Sx and Dx: This set can be used to flag patients who have previously suffered from heat-related illnesses or who are potentially at high risk due to their environmental exposures.
  - Clinical Risk Factors: Identifies patients with underlying conditions such as alcohol abuse that may exacerbate the risk of heat-related illnesses, helping in tailoring preventative measures more effectively.
  - Medication Risk Factors: Some medications can increase susceptibility to heat-related issues by impairing body temperature regulation or hydration status. This value set helps identify patients on such medications.

- Workplace Risk Factors: Some patients may be working in outdoor or indoor environments without adequate cooling or ventilation mechanisms, which would put these individuals at disproportionate risk of experiencing a heat-related event.

- Household Risk factors: Some patients may live in domiciles without adequate cooling or ventilation mechanisms, which would put these vulnerable individuals at disproportionate risk of experiencing a heat-related event.

Disability Status (Under Health Status Assessment):

- AMIA suggests that Disability Status, under Health Status Assessments, be moved to Patient Demographics/Information. The disability community overall has argued that questions to assess disability should be addressed to everyone; they should not single out some people for a report as part of health status.

Medication Administration and Medications Dispensed (Under Medications):

- Clarification is needed for the element "Fill Status." Is such information to be generated by the patient, clinician, an exchange, or pharmacy? Medications - medication reconciliation is a notorious problem and documentation of medication adherence is corollary to that problem. Fill history may be available from some pharmacies as a measure of adherence, but whether the patient is actually taking the medication is largely based on patient self-reporting.

Care Team Member Conducting Health Status Assessment (Under Health Status Assessments):

- Health status assessments will vary by care team member. ASTP/ONC should consider adding an element to identify the care team member conducting the health status assessment, with inclusion of the credential of the care team member. Additionally, it is imperative to consider the sensitivity of the data being collected including the potential misuse of health information and health information technology to investigate and prosecute individuals who can get pregnant, and healthcare professionals trusted with their care

Manufacturer Reference Range (Under Clinical Tests):

- AMIA suggests that ASTP/ONC include an element to specify the underlying procedure/test with inclusion of the manufacturer's specific reference range for each applicable procedure/test.
- Exclude "manufacturer" suggested reference ranges, interpretations; rather what the generating entity uses for reference, interpretation

Individual Administering Vital Signs (Under Vital Signs):

- ASTP/ONC should consider adding elements to identify the role of the individual taking the vital signs, differentiating between inputs that might be from a care team member, or patient or family/caregiver, as separate from an automated device or home monitoring system.

Diagnosis (Under Encounter Information):

- With reference to the Primary Encounter diagnosis field, AMIA encourages ASTP/ONC to replace "diagnosis" with "diagnoses."

Problems (Under Problems):

- Data of Diagnosis and Resolution does not account for the history of the problem/diagnosis/concern. Date of first noted/documented to show historical care would assist in cleaning up the data for reconciliation process.

Lot Number (Under Immunizations):

- AMIA recommends the addition of Lot Number to the Immunizations Data Class. Lot Number will have broad use and impact for immunization safety and effectiveness studies as well as public health surveillance activities. An applicable standard for this data class would be LOINC code: 30959-1 Lot number [Identifier] Vaccine. Manual process for lot number input

We respectfully commend ASTP/ONC for your continued dedication to stakeholder engagement throughout the development of USCDI v6. We welcome the opportunity to support this collaborative process and contribute to the refinement of the standard.

The recommendations outlined in this submission are intended to ensure that USCDI v6 effectively reflects the diverse operational realities of healthcare organizations, enhances the quality and equity of patient care, and strengthens the foundation for meaningful, nationwide interoperability. We look forward to continued dialogue and partnership as this important work progresses.

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Thank you for your time and consideration of these comments. If you have questions or require additional information, please contact Tayler Williams, Senior Manager, Public Policy, at twilliams@amia.org

Sincerely,

Eileen Koski

Chair of the Public Policy Committee